REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): MARK LYTE

PATENT NO.: 5,629,349

ISSUED: MAY 13, 1997

TITLE: COMPOUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

---oOo---

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION FOR BROADENING REISSUE APPLICATION

Sir:

I, Mark Lyte, declare as follows:

STATEMENTS SATISFYING 37 C.F.R. §1.63

I believe that Mark Lyte, 4077 Deerwood Trail, Eagan, Minnesota, 55122, United States, was the original, sole and first inventor of the subject matter which is claimed in U.S. Patent No. 5,629,349 (hereinafter "the LYTE patent") and for which additional claims 3 through 20 are hereby presented in the filing of a Reissue Application (Serial Number 09/---,---, hereinafter the "Reissue Application"), and for which additional claims 3-22 have been submitted for examination in the original filing of the Reissue Application.

I was the owner of the entire right, title and interest in and to the LYTE patent, by virtue of a reassignment from Mankato State University to Mark Lyte, and assigned my entire right, title, and interest to BioNutrix, LLC, in a Contribution Agreement, both title documents being filed with the U.S. Patent and Trademark Office contemporaneously with the filing of this Reissue Application.

I have reviewed and understand the contents of the LYTE patent and the claims submitted to the Patent and Trademark Office upon filing of the Reissue Application.

I hereby offer to surrender U.S. Patent No. 5,629,349 upon granting of the Reissue Application as a Reissue Patent.

STATEMENT SATISFYING 37 C.F.R. §1.175(a)(1)

U.S. Patent 5,629,349 is partly inoperative because the claims include more limitations than were necessary to define over the prior art and are, therefore, unnecessarily narrow.

STATEMENT SATISFYING 37 C.F.R. §1.175(a)(3)

New claims 2 through 22 are being added to the present application, the Reissue Application. The new claims have been added because the claims of the LYTE patent fail to provide an appropriate scope of protection. Accordingly, the new claims are submitted to achieve the protection to which the patent owner is entitled.

Claims 3 through 14

Claims 1 and 2, the only claims issued in the LYTE patent, are overly narrow. Each of claims 1 and 2 fail to claim the broadest protection to which the patent owner is entitled. The errors in the original claims arose approximately December 17-19, 1992, as a result of the applicant's failure to appreciate the scope of the protection to which he was entitled, and the filing of a response with claims that were too narrow and which did not reflect the actual scope of protection to which Applicant was entitled. The errors were, in part, discovered during the applicant's discussions upon issuance of the Patent on May 13, 1997. After discussions with my present attorney, Mark A. Litman, on July 3, 1998, I came to understand that the original claims in the Original Application had been written too broadly, reciting "living organisms," rather than the bacteria, viruses and other microorganisms to which the invention actually pertained. I never appreciated, understood, nor was informed of the fact that the original breadth with respect to enhancing growth was too broad and that the scope of claims could have been narrowed to avoid the art cited in the Office Action. Although I presented arguments to the previous attorney of record, no arguments or amendments were made of record to attempt to counter a rejection which was clearly in error. The degree of error becomes apparent in the section of this Declaration entitled "Review of the Art Cited in a Rejection by the Patent and Trademark Office."

U.S. PAT. NO. 5,629,349 claim 1	REISSUE CLAIM 3
1. A method of suppressing the growth	3. A method of enhancing the growth
of Gram-positive bacteria in a host medium,	of bacteria or viruses
said host medium being selected from the group consisting of in vitro and cell cultures,	said host medium being selected from the group consisting of in vitro and cell cultures,
said method comprising the introduction of an effective amount of a catecholamine to the host medium to act directly on the growth of Gram-positive bacteria.	said method comprising the introduction of an effective amount of a catecholamine to the host medium to enhance the growth of said bacteria or viruses.

As is evident from the above comparison, original claim 1 is limited to the method when employed to inhibit the growth of Gram-positive bacteria *in vitro* or in a cell culture. That is an extremely narrow process of little commercial utility. The original application as filed on March 6, 1992 clearly identified the scope of the invention as including enhancing the growth of bacteria and viruses *in vitro* and in cell cultures. Therefore, the LYTE patent is believed to be defective. New claim 3 recites no such limitations with respect to inhibiting growth in only Gram-positive bacteria. Accordingly, independent claim 3 is submitted to properly claim the broadest improvement over the methods of the prior art to which the patentee is entitled. The new claim 3 also does not contain the limitation that the catecholamine "act directly on enhancing" as I only became aware in my discussions with new counsel, Mark A. Litman, that the actual mechanisms (e.g., direct activity) do not have to be recited in claims. The direct activity is recited in claim 4, and claims dependent therefrom.

These claims were rejected in an Office Action mailed on September 25, 1992 for the following grounds and reasons:

I. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Dyer et al. Or Moger et al. It was asserted that each of the references teaches the affecting of the growth of a vector or cell culture using a catecholamine. This was asserted to be what the Applicant was claiming, and therefore the claims were asserted to not be patentable.

II. Claims 1-23 were rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claim the invention. Certain terms such as "vectors," "analogs" and "derivatives" were held to be indeterminate.

III. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Kotimchenko et al. or Sumanskii et al. Each of the references was asserted to show the use of a neurotransmitter chemical to affect the growth of "living organisms." No patentable distinction was seen between the process of the references and the process of the claims.

The response to this Office Action (filed on December 21, 1992) filed new claims 24-33. A restriction requirement, and an asserted constructive election was erroneously made, the restriction was made as between:

I. Claims 29-33 drawn to a method of diagnosis and glucose production, these claims being held to have been constructively non-elected since they were held to have been not previously examined and their subject matter is new.

II. Claims 24-25 drawn to methods of suppressing growth.

III. Claims 26-28 methods of suppressing growth with a catecholamine blocker.

The attorney of record canceled claims 29-33 and elected claims 24 and 25 for prosecution on the merits. These claims were rejected, an Amendment after Final Rejection was filed and refused admission by an Advisory Action. The Application was then refiled as a File Wrapper Continuation, with only claims 24-28 present in the Application.

A restriction requirement was then filed between claims 24-25 and 26-28 in an Office Action mailed January 31, 1995. Applicant then elected claims 24-25 for prosecution on the merits. These claims were then rejected under 35 U.S.C. 112, first and second paragraphs. After

another series of rejections, with only claims 24-28 in the Application, the two claims in the LYTE Patent were issued.

As is evident from the above comparison, original claim 1 of the LYTE Patent is limited to the method when employed to inhibit the growth of Gram-positive bacteria *in vitro* or in a cell culture. That is an extremely narrow process of little commercial utility. The original application as filed on March 6, 1992 clearly identified the scope of the invention as including enhancing the growth of bacteria and viruses *in vitro* and in cell cultures. Therefore, the LYTE patent is believed to be defective. New claim 3 recites no such limitations with respect to inhibiting growth in only Gram-positive bacteria. Accordingly, independent claim 3 is submitted to properly claim the broadest improvement over the methods of the prior art to which the patentee is entitled.

It is important to note that no restriction requirement in the Application filed on June 27, 1994 was ever asserted against the claims presented in the Reissue Application, so there is no applicability of issues found in *In re Orita, Yahagi, and Enomoti*, 193 USPQ 145, where it was held that "Although appellants undoubtedly erred by failing to file a timely divisional application in order to obtain a divisional patent, it does not follow that such error caused the original patent to be 'partially inoperative by reason of the patentee claiming less than he had a right to claim in the patent' as appellants aver in their reissue declaration under 37 CFR 1.175..." It was further stated in *In re Orita* that "...granting reissue claims substantially identical to those non-elected in application I would be ignoring the proper restriction requirement set forth in that application in which appellants acquiesced. Indeed, appellants' misapplication of section 251 would, if permitted, circumvent the copendency requirement of section 120 incorporated by reference in section." The original restriction requirement was against

1) a method of diagnosing the presence of Gram-negative bacteria, including specific physical steps, none of which are recited in the claims of the Reissue Application;

2) a method of producing glucose from a lactose broth, the claim reciting specific physical steps which are not recited in the claims of the Reissue Application;

3) a method for suppressing the growth of Gram-positive bacteria; and

4) a specific method for suppressing the growth of Gram-negative bacteria comprising the introduction of an effective blocker of catecholamine receptor sites of the organisms.

Methods 1), 2), 3) and 4) are clearly outside the scope of the claimed subject matter of the Reissue Application.

In comparing new claim 3 to original claim 1, claim 1 recites the step of "suppressing the growth of Gram-positive bacteria." Claim 3, however, does not include such a limitation, but instead recites "...enhancing the growth of bacteria or viruses.." This claim is not limited to suppression of growth, but only to enhancing of growth. The only actual restriction requirement which occurred in the prosecution of the U.S. Patent Application U.S. Serial No. 08/266,805 filed on June 27, 1994 was between:

I. Claims 24 and 25, drawn to a method of suppressing the growth of Gram-positive organisms with an amount of catecholamine, classified in Class 514, subclass 727.

II. Claims 26-28, drawn to a method of suppressing the growth of Gram-negative organisms by the introduction of an effective blocker of catecholamine receptor sites of the organisms, classified in Class 514, subclass 224.8.

The constructive election against claims 29-33 found in the parent application preceding U.S. Patent Application U.S. Serial No. 08/266,805 was not a proper restriction requirement, and was substantively incorrect even in its substance. In any event, the claims of the Reissue Application were not the subject of restriction requirements in U.S. Patent Application U.S. Serial No. 08/266,805. Therefore the claims submitted in this Reissue Application do not read on any species, elected invention or non-elected invention for which a proper restriction requirement was made.

In comparing new claim 3 to original claim 1, claim 1 recites the step of "suppressing the growth of Gram-positive bacteria." Claim 3, however, does not include such a limitation, but instead recites "...enhancing the growth of bacteria or viruses.." This claim is not limited to suppression of growth, but only to enhancing of growth. The only restriction requirement which occurred in the prosecution of the U.S. Patent Application U.S. Serial No. 08/266,805 filed on June 27, 1994 was between:

I. Claims 24 and 25, drawn to a method of suppressing the growth of Gram-positive organisms with an amount of catecholamine, classified in Class 514, subclass 727.

II. Claims 26-28, drawn to a method of suppressing the growth of Gram-negative organisms by the introduction of an effective blocker of catecholamine receptor sites of the organisms, classified in Class 514, subclass 224.8.

Therefore the claims submitted in this Reissue Application do not read on any species, elected invention or non-elected invention for which a restriction requirement was made.

In a similar comparison, independent method claim 12 is compared to original method claim 1 for purposes of discussion.

U.S. Pat. No. 5,629,349 claim 1	**REISSUE CLAIM 12**
1. A method of suppressing the growth	12. A method for harvesting the by-products of
of Gram-positive bacteria in a host medium,	enhanced growth of bacteria or viruses comprising
said host medium being selected from the group consisting of in vitro and cell cultures,	introducing an effective amount of a catecholamine to an *in vitro* or cell culture host medium to act directly on enhancing the growth of said bacteria or viruses, and
said method comprising the introduction of an effective amount of a catecholamine to the host medium to act directly on the growth of Gram-positive bacteria.	collecting by-products generated by said bacteria or viruses.

As is evident from the above comparison, original claim 1 is limited to the method when employed to inhibit the growth of Gram-positive bacteria. Accordingly, the claims exclude any useful method of increasing the supply of by-products from said bacteria or cell. The new claim 12 submitted in the Reissue Application encompasses this useful method associated with the enhancement of bacteria or virus growth.

Each of reissue claims 4 through 11 and 13-22 depend from either reissue claim 3 or reissue claim 12, respectively. None of reissue claims 4-11 or 13-22 are believed to be literally restricted to the subject matter which was properly restricted, properly non-elected, and

effectively abandoned in the prosecution of U.S. Patent Application U.S. Serial No. 08/266,805 filed on June 27, 1994 which ultimately issued as U.S. Patent No. 5,629,349 (hereinafter, the "Original Application"). Accordingly, reissue claims 4-11 and 13-22 differ from original claims 1 and 2 and are believed to describe subject matter which is properly the subject of a Reissue Application.

STATEMENT SATISFYING 37 C.F.R. §1.175(a)(5)

During prosecution of the original application, I informed the Attorney of record at the time who was prosecuting the Original Application that the rejection over prior art made in the Office Action mailed on September 25, 1992 was completely erroneous, and that there was absolutely no basis for that rejection being applicable against the scope of invention that I had attempted to cover.

The rejections in the Office Action mailed on September 25, 1992 included rejections of all claims (Claims 1-23) under 35 U.S.C. 102/103 as being unpatentable over Dyer et al., Moger et al., Kotimchenko, or Sukmanskii et al. These rejections were clearly explained to the attorney of record as being completely erroneous, at least for the following reasons:

A. The invention intended to be claimed was the enhanced growth of bacteria or viruses by the administration of catecholamines *in vitro* or in cell cultures. The enhanced growth rate was a result of the addition of the catecholamines.

B. Dyer et al. showed the stimulation of androgen production in ovarian cells when cultured in a serum-free medium. The mechanism proposed in the Chem Abstracts article was that the "catecholamine-augmented androgen prodn. provides a direct link between the autonomic nervous system and regulation of ovarian steroid synthesis." That explanation has no logical bearing or relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference could neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

C. Moger et al. teach that catecholamines stimulated androgen production by mouse interstitial cells in primary culture. The Chem Abstract text has no suggestion on the effect of catecholamine with respect to any cell growth, but only on the stimulation of androgen production. Again, that article has no logical bearing or relationship to the stimulation in the

growth rate of bacteria or viruses, and none was implied by the article. The reference could neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

D. Khotimchenko describes the effect of adrenotropic substances (including ephedrine and noradrenaline) on the oocytes of sea urchins. This article has absolutely no logical relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference could neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

E. Sukmanskii et al. teaches that certain hormones decreased the mitotic index of certain L-cells (reported in the NCBI PubMed QUERY printout as mice cells). The decrease of mitotic activity in mouse L-cells has absolutely no logical relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference could neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

It was absolutely clear to me at the time of reviewing the rejections under 35 USC 102/103 that the rejections were clearly in error with respect to the invention which I thought was being claimed at the time. With the clear instructions and explanations that I gave the attorney, I still do not understand why the rejection was not argued and readily overcome. It was only upon seeing the actual claims which issued in the LYTE Patent on May 13, 1997 that I became aware of and appreciated the error that there were no claims in the LYTE Patent which covered the important invention of enhancing the growth of bacteria and viruses and harvesting by-products of the bacteria and virus.

STATEMENT SATISFYING 37 C.F.R. §1.175(a)(6)

The errors specifically discussed herein arose without any deceptive intention on the part of the applicant. I offer to surrender U.S. Patent No. 5,629,349 to the Patent and Trademark Office in order to obtain a Reissue of that Patent.

STATEMENT SATISFYING 37 C.F.R. §1.175(a)(7)

I acknowledge that I have a duty to disclose information of which I am aware which is material to patentability and the examination of this reissue application in accordance with Title 37, Code of Federal Regulation, Section 1.56.

I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following attorney to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Mark A. Litman, Registration No. 26,390.

Send correspondence to:

Mark A. Litman
Schwegman, Lundberg, Woessner & Kluth, P.A.
1600 TCF Tower
121 South Eighth Street
Minneapolis, MN 55402

Direct telephone calls to:

Mark A. Litman
(612) 373-6975

Respectfully submitted,

Dated: 2/1/99

Mark Lyte

REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark Lyte
Serial No.: Unknown
Filed: Concurrently Herewith Docket: 933.001USR
Title: COMPOUNDS FOR MODULATING GROWTH OF INFECTIOUS AGENTS

ASSENT BY ASSIGNEE UNDER 37 C.F.R. § 1.172 AND POWER OF ATTORNEY

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

BioNutrix, LLC, being the Assignee of the entire interest in and to U.S. Patent No. 5,629,349, issued on May 13, 1997, to Mark Lyte and entitled "Compounds for Modulating Growth of Infectious Agents", hereby assents to the reissue of said patent.

Assignee hereby appoints:

Anglin, J. Michael	Reg. No. 24,916	Klima-Silberg, Catherine I.	Reg. No. 40,052
Arora, Suneel	Reg. No. 42,267	Kluth, Daniel J.	Reg. No. 32,146
Bianchi, Timothy E.	Reg. No. 39,610	Lacy, Rodney L.	Reg. No. 41,136
Billion, Richard E.	Reg. No. 32,836	Leffert, Thomas W.	Reg. No. 40,697
Black, David W.	Reg. No. 42,331	Lemaire, Charles A.	Reg. No. 36,198
Brennan, Thomas F.	Reg. No. 35,075	Litman, Mark A.	Reg. No. 26,390
Brooks, Edward J., III	Reg. No. 40,925	Lundberg, Steven W.	Reg. No. 30,568
Clark, Barbara J.	Reg. No. 38,107	Mates, Robert E.	Reg. No. 35,271
Drake, Eduardo E.	Reg. No. 40,594	McCrackin, Ann M.	Reg. No. 42,858
Dryja, Michael A.	Reg. No. 39,662	Padys, Danny J.	Reg. No. 35,635
Embretson, Janet E.	Reg. No. 39,665	Polglaze, Daniel J.	Reg. No. 39,801
Fogg, David N.	Reg. No. 35,138	Schwegman, Micheal L.	Reg. No. 25,816
Forrest, Bradley A.	Reg. No. 30,837	Sieffert, Kent J.	Reg. No. 41,312
Harris, Robert J.	Reg. No. 37,346	Slifer, Russell D.	Reg. No. 39,838
Holloway, Sheryl S.	Reg. No. 37,850	Terry, Kathleen R.	Reg. No. 31,884
Huebsch, Joseph C.	Reg. No. 42,673	Viksnins, Ann S.	Reg. No. 37,748
Kalis, Janal M.	Reg. No. 37,650	Woessner, Warren D.	Reg. No. 30,440

as its attorneys, with full power of substitution and revocation, to prosecute the reissue application, to make alterations and amendments therein, and to transact all business in the U.S.